



FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT &amp; TRADEMARK OFFICE

SHEET 1 OF 1  
(REV. 7-8)

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**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 0630/1G704US2 SERIAL NO: 09/924,944  
APPLICANT: Douglas C. Harnish FILING DATE: 08/08/01  
CONFIRMATION NO: TBA

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
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**FOREIGN PATENT DOCUMENTS**

*EXAMINER INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
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my 1. WO 99/07847 2/18/99 PCT

**OTHER REFERENCES****(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

\*EXAMINER  
INITIALS

- my  
↓
2. Kuiper *et al.*, Proc.Natl.Acad.Sci.USA 93:5925, 1996
  3. Mosselman *et al.*, FEBS Letts. 392:49, 1996
  4. Breckenridge *et al.*, Atherosclerosis, 45:161, 1982
  5. Goldberg *et al.*, J. Clin. Invest. 70:1184, 1982
  6. Homanics *et al.* J. Biol. Chem. 270:2974, 1995
  7. Clay *et al.* Biochim. Biophys. Acta. 1002:173, 1989
  8. Busch *et al.* J. Biol. Chem. 269:16376, 1994
  9. Fan *et al.* PNAS 91:8724, 1994
  10. Tikkanen *et al.* Acta Obstet Gynecol Scand Suppl. 88:83, 1979

EXAMINER:

Mish y

DATE CONSIDERED:

6-10-03

\*EXAMINER:

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,944	08/08/2001	Douglas C. Harnish	0630/1G704US2	2000

32801 7590 06/16/2003

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EXAMINER
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YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/924,944

Applicant(s)

HARNISH ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the process claims should be rejoined under In re Ochiai. This is not found persuasive because the products are not allowable. See claims rejection below.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's request to rejoin claim 25 with the elected invention is persuasive.

Claims 1-25 are pending and claims 12-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claims 1-11, and 25 are examined on merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites "the transformed cells are present in a number in a single assay system" but it is not clear what the metes and bounds are for the limitation.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harnish et al (1998, J. Biol. Chem. vol. 273, pages 9270-8) and Ameis et al (1990, J. Biol. Chem. vol. 265, pages 6552-5) in view of Norris et al (1995, J. Biol. Chem. vol. 270, pages 22777-82), US Pat 5,908,859 (June 1, 1999, or Dichek et al (1998, J. Biol. Chem. vol. 273, pages 1896-903).

Claims 1-10 and 25 are interpreted as drawn to recombinant cell (more specifically a hepatocarcinoma cell in claim 9, HepG2 cell in claim 10) containing 3 DNA constructs, i.e. 1) DNA construct expressing a estrogen receptor (more specifically human one in claim 2, human estrogen receptor alpha (ER-alpha) in claim 3); 2) DNA construct expressing a transcription coactivator C/EBP; 3) a reporter construct linking various art-known reporters listed in claim 7 (more specifically luciferase in claim 8) to hepatic lipase promoter/enhancer (more specifically -1557 to +43 of human HL gene in claim 6). Claim 11 is interpreted as drawn to the recombinant cell of claim 1 for screening useful compounds affecting the ERalpha and/or C/EBP dependent transcription activation of hepatic lipase promoter/enhancer in multi-well format capable of detecting the reporter being used.

The primary references (Harnish et al and Ameis et al) teach all the materials and/or technology necessary to make and use the claimed invention. Ameis et al teach

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at Fig. 3 a human HL promoter/enhancer (−1557 to +43). Harnish et al teach the rest of materials to make and use the instant invention: HepG2 cells and other cells; a DNA construct expressing a estrogen receptor, more specifically human ER-alpha, the ER-alpha used is a human origin as evidenced by Kumar et al (1987, Cell vol. 51, pages 941-51 abstract only); a DNA construct expressing a transcription coactivator C/EBP; 3) a reporter construct linking various art-known reporters to a promoter/enhancer of interest (in the case of Harnish et al, apoA1). Note the entire article, especially Materials and Methods section at page 9271. Harnish et al further teach the reason for using a vector expressing transcription coactivator C/EBP in the study of ER-alpha regulated transcription activity is because the transcription factor is involved in the ER-alpha function. See the paragraph bridging page 9270-1. Harnish et al also teach why HepG2 is used in ER-alpha dependent transcription study. See page 9271, Right column, 2<sup>nd</sup> paragraph.

Any of the secondary references teaches why one of ordinary skill would be motivated to choose the human HL promoter/enhancer (−1557 to +43) taught by Ameis et al as a promoter/enhancer of interest, i.e. hepatic lipase gene might be regulated by estrogen receptor and regulating the hepatic lipase gene might be a good target in preventing heart diseases and other lipid-metabolism-related diseases in menopausal women. Note the entire Dichek et al; columns 1-2 of the '859 patent; Materials and Methods at page 22777-8, and the last paragraph of Norris et al. As for claim 11, Norris et al teach that multi-well plates could be used in screening assay involving detection of luciferase activity; note 2<sup>nd</sup> paragraph at page 22778 and Fig. 2.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make and use the claimed invention with reasonable expectation of success.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu  
June 11, 2003

  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800-1600